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Research Article

COMPAIRATIVE STUDY OF VARIOUS FORMULATION OF BI LAYERED FLOTTING TABLET OF SUSRALFATE AND METOPROLOL SUCCINATE

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ABSTRACT

Comparing the results of post compresional parameters and drug release study within Best formulations (SFMS), Developed formulations(DSFMS) ,Optimized formulation (OSFMS) selected from 15 formulations of Sucralfate and 10 formulations of Metoprolol Succinate. The Bi Layered Floating Tablets are compressed by the selective formulations and Post compresional parameters ; Avrage weight, thickness, Hardness,% friability, DT of Sucralfate layer, FLT and TFT of Metoprolol Succinate Layer,Drug content ,stability study,Kinetic drug release profile are studied and best formulation among them are selected. Post compressional parameters of the formulations (SFMS), (DSFMS) ,(OSFMS) full fill parameters of Bi layered Floating Tablet but DSFMS produce TFT is 24 hrs and produce better release than others. Conclusion: DSFMS produce DT 2.04± 0.157 min ,FLT 10sec,TFT >24hrs,and drug content 99.23% of Sucralfate and 100.06% of Metoprolol Succinate .So it is confirmed that the formulation (DSFMS) produce better Bi layered Floating Tablet .

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INTRODUCTION

Good quality drugs fulfilling the regulatory parameters and produced per the current good manufacturing (CGMP) standards (Haile K *et al* ,2018) are very critical for best therapeutic outcome in patient therapy. Comparative study provide better formulation among all.

Bilayer floating drug delivery system is combined principle of Bi –Layered Tablet as well as floating mechanism(Pathekar S *et al* ,2016) Drug absorption from G.I.T depends upon contact time with intestinal mucosa (Arora S *et al*, 2005) Bi-layered Tablet materials involve both the compressibility and consolidation (Verma R *et al* ,2014) Bi-Layered tablet contain immediate and sustained release layer (Biswal B *et al* ,2011).

The incorporated drug remain in gastric region for several hours and produce prolong gastric resistance time and improve bioavailability .It reduce drug waste and enhance the solubility of drug (Garg R K *et al*, 2015).

The drug release slowly at desired rate and increase GRT .and better control of fluctuations in plasma drug concentration . (Kardumpala S *et al*, 2013).Both Sucralfate and Metoprolol succinate produce minor drug interaction in pregnancy and lactate mother (Regardh CG *et al*, 1981).

Both the drugs are administrated in empty stomach in presence of acid medium They act at stomach as well as at upper part of small intestine and produce better bioavilability (Wakade R.B *et al* 2013).

The present study is to develop and to optimize.(Rajendra K *et al* ,2016) Bi-Layered Floating Tablet of Sucralfate and Metoprol succinate to formulate a new formulation producing better release at low dose. and to make a comparison study between the initial formulation and optimized formulation

METERIALS AND METHODS

Selected formulation of Immediate Release Sucralfate layer and floating Sustained Release Metoprolol Succinate layer are taken and following methods; Preformulation studies, Preparation of granules, Preparation of Tablet, The Post comprisal parameters of formulations, Acclerated stability study, Release kinetic profile study are applied and best formulations among them are selected.

Selection of Best formulations (SFMS) selected from 15 formulations of Sucralfate and 10 formulations of Metoprolol Succinate.

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Table 1 Composition of 15 formulations of Sucralfate Immidiate release layer.(SF1-SF9)

	Ingredients	*Quantity Per Tablet in mg*								
		SF 1	**SF 2**	**SF 3**	**SF 4**	**SF 5**	**SF 6**	**SF 7**	**SF 8**	**SF 9**
1	Sucralfate	100	100	100	100	100	100	100	100	100
2	Crospovidone	0	6.25	6.25	6.25	6.25	6.25	6.25	6.25	6.25
3	Calcium carbonate	23	25	25	25	0	25	0	0	0
4	Aerosil	1	1	1	1	1	1	1	1	1
5	Lactose MHF	31.25	31.25	31.25	31.25	31.25	31.25	31.25	31.25	31.25
6	MCC PH 101	48.45	45.2	44.575	44.575	74.575	49.575	49.575	49.825	46.075
7	Magnesium Stearate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
8	Sodium bicarbonate	5	5	5	5	0	0	25	25	25
9	Polysorbate 80	0	0	0	0.625	0.625	0.625	0.625	0.375	0.375
10	SLS	0	0	0.625	0	0	0	0	0	0
11	Sunset yellow	0.312	0.3125	0.3125	0.3125	0.3125	0.3125	0.3125	0.3125	0.3125
12	Purified Water	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s
	Totalwt	214.5	214.5	214.5	214.5	214.5	214.5	214.5	214.5	214.5

Table 2 Composition of 15 formulations of Sucralfate Immidiate release layer (SF10-SF15)

Sl No	***Ingredients***	***Quantity Per Tablet In Mg***					
		SF 10	**SF 11**	**SF12**	**SF 13**	**SF 14**	**SF 15**
1	Sucralfate	100	100	100	100	100	100
2	Crospovidone	6.25	6.25	3.75	8.75	6.25	6.25
3	Aerosil	1	1	1	1	1	1
4	Lactose MFL	31.25	31.25	31.25	31.25	31.25	31.25
5	MCC PH101	48.575	43.575	48.575	43.575	52.325	39.825
6	Magnesium Stearate	0.5	0.5	0.5	0.5	0.5	0.5
7	Sodium Bicarbonate	25	25	25	25	18.75	31.25
8	Polysorbate 80	0.375	0.375	0.375	0.375	0.375	0.375
9	HPC-L	1.25	6.25	3.75	3.75	3.75	3.75
10	Sunset Yellow	0.3125	0.3125	0.3125	0.3125	0.3125	0.3125
11	Purified Water	q.s	q.s	q.s	q.s	q.s	q.s
	Total Weight	214.5	214.5	214.5	214.5	214.5	214.5

Table 3 Composition of10 formulations of floating Sustained Release MetoproloSuccinate tablets

SL. NO	**Ingredients**	**QUANTITY PER TABLET IN MG**									
		F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**	**F10**
1	Metoprolol succinate	50	50	50	50	50	50	50	50	50	50
2	Hpmc k 100m	100	100	100	100	100	100	100	100	100	75
3	Sodium bicarbonate	75	100	100	100	100	100	100	100	100	100
4	Aerosil	3	3	3	3	3	3	3	3	3	3
6	Eudragit rspo	30	30	-		-	-	-	-	-	30
7	Eudragit rlpo	-	-	30		-	-	-	-	-	-
8	Eudragit rs100	-	-		30	-	-	-	-	-	-
8	Na cmc	-	-	-	-	30	-	-	-	-	-
9	Sodium alginate	-	-	-	-		30	-	-	-	-
10	Hpc klucel hf	-	-	-	-	-	-	30	-	-	-
11	Pvpk 90	-	-	-	-	-	-	-	30	-	-
12	Ethyl cellulose	-	-	-	-	-	-	-	-	30	-
13	Talc	3	3	3	3	3	3	3	3	3	3
14	Ipa	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
15	Purified water	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
	Total weight	261	286	286	286	286	286	286	286	286	261

Table 4 Composition of formulation of Sucralfate and Metoprolol Succinate(SFMS) Bi Layered Floating Tablet.

SL No	**INGREDIENTS (mg)**	**SF 10**	**INGREDIENTS (mg)**	**MSF6**
1	*Sucralfate*	100	*Metoprolol Succinate*	50
2	*Crospovidone*	6.25	HPMC K 100M	100
3	*Aerosil*	1	Sodium Bicarbonate	100
4	*Lactose MFL*	31.25	Aerosil	3
5	*MCC PH101*	48.575	Eudragit RSPO	30
6	*Magnesium Stearate*	0.5	Eudragit RLPO	-
7	*Sodium Bicarbonate*	25	Eudragit RS100	-
8	*Polysorbate 80*	0.375	NA CMC	-
9	*HPC-L*	1.25	Sodium Alginate	-
10	*Sunset Yellow*	0.3125	HPC Klucel HF	-
11	*Purified Water*	q.s	Pvpk 90	-
	Total Weight	214	Ethyl Cellulose	-
12			Talc	3
13			IPA	Q.S
14			PURIFIED WATER	Q.S
15			TOTAL WEIGHT	286

Selection of Best formulations (DSFMS) selected from 15 formulations of Sucralfate and 10 formulations of Metoprolol Succinate (SF9+MSF10)

Table 5 Composition of 10 formulations of Sucralfate Immidiate release layer

	Ingredients	*Quantity Per Tablet in mg*									
		SF 1	**SF 2**	**SF 3**	**SF 4**	**SF 5**	**SF 6**	**SF 7**	**SF 8**	**SF 9**	**SF10**
1	Sucralfate	100	100	100	100	100	100	100	100	100	100
2	Sodium CMC	0	5.84	6,5	7.1	8	3.4	8.5	6	12.5	3.505
3	Calcium Phosphate	17.5	24.46	25.73	8.2	8.8	5.4	10.2	19.3	1.3	22.97
4	MCC	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
5	Sodium bicarbonate	90	85	80	90	90	85	90	85	90	80
6	Magnesium oxide	75	80	85	90	85	90	80	75	85	85
7	Aerosil/ colloidal SiO2	3.8	3	1	2	1	3	1	2	2	1
8	Hydroxy Propyl Methyl Cellulose	10	0	0	0	5	10	5	10	5	5
9	Sodiumlaurylsulfate	0	0	0	1	0.5	1.5	2	0.5	2.5	0
10	Alginic Acid	0	0	1.07	0	0	0	0	0	0	0.625
11	Magnesium Stearate	2.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
12	Sunset Yellow	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s
13	SLS	0	0	0.2	0	0.2	0	0.5	0.5	0	0.2
	TOTAL	300	300	300	300	300	300	300	300	300	300

Table 6 Composition of10 formulations of floating Sustained Release Metoprolol Succinate tablets.

Sl. No	**Ingredients**	**QUANTITY PER TABLET IN MG**									
		MSF1	**MSF2**	**MSF3**	**MSF4**	**MSF5**	**MSF6**	**MSF7**	**MSF8**	**MSF9**	**MSF10**
1	Metoprolol Succinate	50	50	50	50	50	50	50	50	50	50
2	Ethyl cellulose	50	50	50	50	45	50	45	45	50	50
3	Xanthan Gum	50	-	-	-	50	-	-	-	50	-
4	Metoloze	-	50	-	-	-	50	-	-	-	50
6	Polyox	-	-	50	-	-	-	50	-	-	-
7	Eudragit	-	-	-	50	-	-	-	50	-	-
8	Methocel	25	-	25	-	25	-	25	-	25	-
8	Acrilic acid	-	25	-	25	-	25	-	25	-	25
9	Aerosil/ colloidal SiO2	15	15	15	15	15	15	15	15	15	15
10	Talc	5	5	5	5	10	5	10	10	5	5
11	Isopropyl alcohol (IPA)	QS	QS	QS	QS	QS	QS	QS	QS	QS	QS
12	Purified water	QS	QS	QS	QS	QS	QS	QS	QS	QS	QS
13	Sodium Bicarbonate	5	5	5	5	5	5	5	5	5	5
	TOTAL WEIGHT	200	200	200	200	200	200	200	200	200	200

Table 7 Composition of developed formulation of Sucralfate and Metoprolol Succinate (DSFMS) Bi Layered Floating Tablet.

SL.NO	***Ingredients of best formulation(Sf9)***	***Quantity per tablet in mg***	**Ingredients Of Best Formulation (Msf10)**	***Quantity per tablet in mg***
1	Sucralfate	**100**	Metoprolol Succinate	**50**
2	Sodium CMC	**12.5**	Ethyl cellulose	**50**
3	Calcium Phosphate	**1.3**	Xanthan Gum	**-**
4	MCC	**1.5**	Metoloze	**50**
5	Sodium bicarbonate	**90**	Polyox	**-**
6	Magnesium oxide	**85**	Eudragit	**-**
7	Aerosil/ colloidal SiO2	**2**	Methocel	**-**
8	Hydroxy Propyl Methyl Cellulose	**5**	Acrilic acid	**25**
9	Sodiumlaurylsulfate	**2.5**	Aerosil/ colloidal SiO2	**15**
10	Alginic Acid	**0**	Talc	**5**
11	Magnesium Stearate	**0.2**	Isopropyl alcohol (IPA)	**QS**
12	Sunset Yellow	**qs**	Purified water	**QS**
13	SLS	**0**	Sodium Bicarbonate	**5**
	Total Weight	**300**	**Total weight**	**200**

Selection of Optimized formulations (OSFMS) selected from 15 formulations of Sucralfate and 10 formulations of Metoprolol Succinate :

Table 8 Composition of 15 formulations of Sucralfate Immidiate release layer :(SF1-SF9)

	Ingredients	*Quantity Per Tablet in mg*								
		SF 1	**SF 2**	**SF 3**	**SF 4**	**SF 5**	**SF 6**	**SF 7**	**SF 8**	**SF 9**
1	Sucralfate	100	100	100	100	100	100	100	100	100
2	Crospovidone	0	6.25	6.25	6.25	6.25	6.25	6.25	6.25	6.25
3	Calcium carbonate	23	25	25	25	0	25	0	0	0
4	Aerosil	1	1	1	1	1	1	1	1	1
5	Lactose MHF	31.25	31.25	31.25	31.25	31.25	31.25	31.25	31.25	31.25
6	MCC PH 101	48.45	45.2	44.575	44.575	74.575	49.575	49.575	49.825	46.075
7	Magnesium Stearate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
8	Sodium bicarbonate	5	5	5	5	0	0	25	25	25
9	Polysorbate 80	0	0	0	0.625	0.625	0.625	0.625	0.375	0.375
10	SLS	0	0	0.625	0	0	0	0	0	0
11	Sunset yellow	0.312	0.3125	0.3125	0.3125	0.3125	0.3125	0.3125	0.3125	0.3125
12	Purified Water	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s
	Total wt of Tablet	214.5	214.5	214.5	214.5	214.5	214.5	214.5	214.5	214.5

Table 9 List of excipients used for the preparation of Sucralfate layer (SF10---SF15)

Sl No	*Ingredients*	*Quantity Per Tablet In Mg*					
		SF 10	**SF 11**	**SF12**	**SF 13**	**SF 14**	**SF 15**
1	Sucralfate	100	100	100	100	100	100
2	Crospovidone	6.25	6.25	3.75	8.75	6.25	6.25
3	Aerosil	1	1	1	1	1	1
4	Lactose MFL	31.25	31.25	31.25	31.25	31.25	31.25
5	MCC PH101	48.575	43.575	48.575	43.575	52.325	39.825
6	Magnesium Stearate	0.5	0.5	0.5	0.5	0.5	0.5
7	Sodium Bicarbonate	25	25	25	25	18.75	31.25
8	Polysorbate 80	0.375	0.375	0.375	0.375	0.375	0.375
9	HPC-L	1.25	6.25	3.75	3.75	3.75	3.75
10	Sunset Yellow	0.3125	0.3125	0.3125	0.3125	0.3125	0.3125
11	Purified Water	q.s	q.s	q.s	q.s	q.s	q.s
	Total Weight	214.5	214.5	214.5	214.5	214.5	214.5

Table 10 List of excipients used for the preparation of Metoprolol Succinate sustained release layer

SL. NO	INGREDIENTS	QUANTITY PER TABLET IN MG									
		MSF1	**MSF2**	**MSF3**	**MSF4**	**MSF5**	**MSF6**	**MSF7**	**MSF8**	**MSF9**	**MSF10**
1	Metoprolol Succinate	50	50	50	50	50	50	50	50	50	50
2	HPMC K 100M	100	100	100	100	100	100	100	100	100	75
3	SODIUM BICARBONATE	75	100	100	100	100	100	100	100	100	100
4	AEROSIL	3	3	3	3	3	3	3	3	3	3
6	EUDRAGIT RSPO	30	30	-		-	-	-	-	-	30
7	EUDRAGIT RLPO	-	-	30		-	-	-	-	-	-
8	EUDRAGIT RS100	-	-		30	-	-	-	-	-	-
8	Na CMC	-	-	-	-	30	-	-	-	-	-
9	SODIUM ALGINATE	-	-	-	-		30	-	-	-	-
10	HPC KLUCEL HF	-	-	-	-	-	-	30	-	-	-
11	PVPK 90	-	-	-	-	-	-	-	30	-	
12	ETHYL CELLULOSE	-	-	-	-	-	-	-	-	30	-
13	TALC	3	3	3	3	3	3	3	3	3	3
14	IPA	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
15	PURIFIED WATER	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S

Table 11 Composition of formulation of Optimized Sucralfate and Metoprolol Succinate (OSFMS) Bi Layered Floating Tablet.

SL No	*Ingredients*	Quantity per Ingredients in mg(Optimized Sucralfate Layer)	*Ingredients*	Quantity per Ingredients in mg (Optimized Metoprolol Succinate Layer)
1	SUCRALFATE	100	*Metoprolol Succinate*	50
2	CROSS POVIDONE	7	HPMC K 100 M	25
3	AEROSIL	1	SODIUM BICARBONATE	15
4	LACTOSEMFL	31.25	AEROSIL	3
5	MCC PH101	43.575	EUDRAGIT-RSPO	20
6	SODIUM BICARBONATE	15	EUDRAGIT-RLPO	7.5
7	POLYSORBATE 80	7	EUDRAGIT-RS100	5
8	HPC-L	5	Na CMC	17.5
9	MAGNESIUM STEARATE	3.75	SODIUM ALGINATE	15
10	SUNSET YELLOW (0.25%)	0.3125	HPC	12.5
11	PURIFIED WATER	qs	ETHYL CELLULOSE	10
	TOTAL WEIGHT	214	PVPK -90	2.5
12			TALC	3
13			IPA	Q.S
14			PURIFIED WATER	Q.S
15			TOTAL WEIGHT	186

Optimization of Sucralfate formulation

15 formulations of Sucralfate and 10 formulations of Metoprolol Succinate is taken. By changing the concentration of Superdisintigrant, Surfectants, Alkalizing agents & Binding agents of Sucralfate and changing concentrations of Alkalizing agents and Polymers of Metoprolol Succinate the OSFMS (Optimized Sucralfate and Metoprolol Succinate Formulation) is generated.

These in-vitro drug release studies of Sucralfate and Metoprolol Succinate layers were carried out as per USP guidelines.

The dissolution method and equipment were validated before the study. The dissolution of all batches of tablets was carried out using LABINDIA DISSO 2000 with automatic sampler, a USP Apparatus-II Paddle type apparatus with 0.1N HCl (and 6.8pH phosphate buffer respectively) as dissolution media with volume of 900ml. The dissolution medium was subjected to degassing by placing the dissolution vessel with medium in a water bath at 37 ± 2^0C. The paddle speed was set at 75rpm and the temperature was maintained at 37 ± 0.5^0C. The sampling volume was 10ml with a rinsing volume of 3ml and with 10ml replacing volume. The sampling intervals were 5, 10, 15, 20, 30 and 45minutes. The collected samples were analyzed as pooled samples at 281nm using UV-Spectrophotometer.

Preparation and in–vitro evaluation of Bi Layered Floating Tablet of selected formulations (SFMS,DSFMS and OSFMS) of Sucralfate and Metoprolol Succinate.

Preformulation study

The preformulation studies like flow properties, solubility were determined.

Flow properties are studied of Sucralfate and Metoprolol succinate formulations.

The following flow properties of the lubricated granules were evaluated.

Angle of Repose (Θ): It was determined by using a funnel whose tip was fixed at a constant height (H) of 2.5cm from horizontal surface. The granules and the powder were passed separately through the funnel until the tip of the conical pile touches the tip of the funnel. The radius of the base of the conical pile is measured as R (cm). It is determined with the formula;

Angle of repose (θ) = Tan^{-1} (height of pile /radius of pile).

Angle of Repose	Powder flow
< 25	Excellent
25-30	Good
30-40	Passable
< 40	Very poor

Bulk density and Tapped density (g/ml)

The previously weighed pure drug or granules (W) were placed separately into a graduated measuring cylinder and the initial (bulk) volume (V_B) was noted. It was placed in the tapped density tester USP and subjected to constant tapping at a rate of 200drops/min until the difference between the initial and final volumes should be less than 2%. It was recorded as the final (tapped) volume (V_T) and various flow properties were calculated with the following formulae.

Bulk density, $\rho B = \frac{W}{VB}$ Tapped density, $\rho T = \frac{W}{VT}$

Compressibility Index

It was calculated by using the following formula

Carr's Index or Compressibility Index (CI) = $1-\frac{\rho B}{\rho T} * 100$

The CI value below 15% indicates good flow of the powder and above 30% indicates poor flow property of the powder.

Hausner's Ratio: It is calculated by the following formula;

Hausner's Ratio= $\frac{\rho T}{\rho B}$

The Hausner's ratio below 1.25 indicates good flow property and above 1.25 indicates poor flow property of the powder.

Preparation of Granules

Preparation of Sucralfate Granules

The10 formulations of Sucralfate IR tablets were prepared by wet granulation method**.** The composition of the tablet is mentioned in The required ingredients were weighed accurately and passed through 40 mesh. The sieved materials were then mixed well in a poly bag for about 30 minutes. The surfactants, Alginic acid were dissolved in cold and hot water respectively to use as granulating fluid. To moisten the blend, either water or surfactant solution was used as granulating fluid. The wet mass was granulated in RMG granulator. The granules were then dried in a Retsch rapid dryer at 60^0C for about 60 minutes until the % LOD becomes less than 3%. The dried granules were then passed through 40 mesh and then lubricated by mixing with the lubricant (which was previously passed through 60 mesh) in a polybag for about 15 minutes. The flow properties of the lubricated granules were determined.

Preparation of Metoprolol Succinate Granules

The Metoprolol Succinate floating SR granules were prepared by wet granulation method. The composition of the tablets is given in · The drug and polymer which were previously passed through 40 mesh were mixed thoroughly in a polybag for 20 minutes. The blend was moistened with granulating fluid *i.e.,* water and IPA (1:9 parts). The wet mass was passed through 24 mesh and then dried in a tray dryer at 50^0C for about 50 minutes until the % LOD becomes less than 2%. The dried granules were passed through 30 mesh and mixed with sodium bicarbonate in a polybag for 10 minutes. To this talc (previously passed through 60mesh) was added and mixed well for 10 minutes. The flow properties of the lubricated granules were evaluated.

Preparation of Tablet

Preparation of Sucralfate (IR) layer in BIlayer Floating Tablet

The lubricated granules were then compressed by using 16 station tablet compression machine (CADMACH) with 7 mm plane round shaped punches. 10 formulations of Sucarlfate tablet are made of different compositions

Preparation of Metoprolol Succinate (SR) tablet

The lubricated granules were compressed by 16 station tablet compression machine (CADMACH) with 13.1mm round concave punches. The 10 formulations of different compositions are made

The Post comprisal parameters of formulations of Sucralfate and Metoprol Succinate.

According to IP the Post comprisal parameters like hardness, thickness,% friability, disintegration time were evaluated for all the prepared tablets. The drug content was determined for all the batches. Dissolution studies were conducted for all formulations.

Weight variation

Twenty tablets were collected randomly and the average weight and individual weight was calculated. The % weight variation was calculated with the following formula.

%Weight variation= Average weight-individual weight/individual weight x100

Thickness

The thickness of the ten tablets was measured in mm by using Vernier calipers.

Hardness

The hardness of the ten tablets was measured by using Varian V K200 Tablet Hardness Testerand is given in the units of KP.

Friability

Ten tablets were carefully dedusted prior to testing and weighed accurately (Wo). The tablets were placed in the drum of Roche Friabilator (USP). The drum was rotated for 100 times at a speed of 25rpm. The tablets were collected, re-dedusted and accurately weighed (W1). It is calculated form the following formula;

$$\%\ Friability = 1 - \frac{W1}{W0} * 100$$

Disintegration Test

The disintegration study was performed for Sucralfate tablets by using disintegration apparatus Thermonik DT Tester (USP). For this water was used as the disintegration medium. 6 tablets were placed in 6 tubes of the disintegration apparatus. The time (min) taken for the tablets to disintegrate was noted.

Floating lag time (FLT)

The MS tablets were placed in a beaker containing 250ml of 0.1N HCl and the time (sec) required to float the tablet was observed and recorded as FLT.

Total floating time (TFT)

The time (hr) up to which the MS tablet remains buoyant w Determination of drug content of Sucra as noted and recorded as TFT.

lfate Metoprolol Succinate Layers.

Ten SF tablets were weighed accurately and then crushed well in a clean motor and pestle. The powder equivalent to 25mg of the drug was weighed (Ws) and then transferred to a 100ml volumetric flask. 50ml methanol was added and sonicated for 5 minutes at 27^0C. Then the volume was made up to 100ml using methanol (V4). From this 4ml (V5) was transferred to a 100ml volumetric flask and the volume was made up to 100ml (V6) with 0.1N HCl (pH 1.2). The flask was agitated for 5 minutes and then the sample was analyzed for drug content at 281nm using UV Spectrophotometer. The drug content was calculated using the following formula.

$$\textbf{\% Drug Content} = \frac{AS}{AS} * \frac{W}{V1} * \frac{V2}{V3} * \frac{V4}{WS} * \frac{V6}{V5} * \frac{AW}{L} * P$$

Where,

AS= Test absorbance
AS= Standard Absorbance
W= Weight of standard drug (25mg)
V1= Volume of solvent added to standard stock solution (100ml)
V2, V3= Dilution of the standard stock solution (4ml of stock solution diluted to 100ml with solvent)
AW= Average weight of the tablet (mg)
L= Label claim of the drug (10mg)
P = Potency of sucralfate (91.4%).

Determination of drug content of Metoprolol Succinate tablets

Ten MS tablets were weighed and crushed in a motor with pestle. The crushed powder equivalent to 100mg of MS (WS) was weighed accurately and transferred to a clean, dried 100ml volumetric flask. 50 ml of 0.1N HCl was added and agitated vigorously for 10 minutes and sonicated for 4 hours. The final volume was made up to 100ml (V4) using 0.1N HCl and agitated for 5 minutes. A portion of it was centrifuged at 300 rpm for 10 minutes. The centrifuged sample was filtered through 0.45µm whatmann filter paper. 2 ml (V5) of the filtered sample was pipetted out and transferred to a 100ml volumetric flask and the volume was made up to 100ml (V6) with 0.1N HCl and the flask was shaked for 5 minutes. The sample was then analyzed for the drug content at 233nm using UV Spectrophotometer. The drug content was calculated using the following formula.

$$\textbf{\% Drug Content} = \frac{AS}{AS} * \frac{W}{V1} * \frac{V2}{V3} * \frac{V4}{WS} * \frac{V6}{V5} * \frac{AW}{L} * P$$

AS= Test absorbance,AS= Standard Absorbanc,W= Weight of standard drug (100mg)

V1= Volume of solvent added to standard stock solution (100ml),V2, V3= Dilution of the standard stock solution (2ml of stock solution diluted to 100ml with solvent),Aw= Average weight of the tablet (mg),L= Label claim of the drug (375mg),P = Potency of metoprolol succinate (99.83%)

Table 1 Comparative Post compressional study of (SFMS), (DSFMS), (OSFMS)

Sl No	parameters	observed value(sfms)	observed value(dsfms)	observed value(osfms)
1	Average Weight (mg)	494.7±0.866	500.7±0.866	500±0.379
2	Thickness (mm)	5.89±0.136	5.71±0.032	5.21±0.125
3	Hardness (KP)	8.3±0.348	7.2±0.312	8.1±0.291
4	% Friability	0.646	0.712	0.543
5	FLT (sec)	785	10	755
6	TFT (hr)	>20	>24	6.45>24
7	DT of sucralfate layer	2.02±0.157	2.04±0.157	1.04±0.154
8	Drug Content of Sucralfate	99.95 %	99.23%	99.78%
9		102.11 %	100.06%	100.06%

DISCUSSION

Post compressional parameters of the formulations (SFMS), (DSFMS) ,(OSFMS) produce better resultant and fullfill the requirements of Bi layered Floating Tablet and resultants are equivalent to each other but in case of DSFMS total floating hours is 24 hrs which is more than other.So it can provide better Gastro retaintaion.

It is concluded tha**t** in presence of maximum % of Sodium bicarbonate, Magnesium oxide, and Sodium CMC the Sucralfate layer and In presence of maximum % of Metoloze, Acrilic acid, and Aerosil ,in vitro evaluation of DSFMS produce DT 2.04± 0.157 min ,FLT 10sec,TFT >24hrs,and drug content 99.23% of Sucralfate and 100.06% of Metoprolol Succinate .So it is confirmed that the formulation (DSFMS) produce better Bi layered Floating Table

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